REMARKS

Pending claims

Applicants note that Claims 8, 17-27, and 30-45 were canceled in the Transmittal filed May 4, 2001. Applicants note that Groups 1, 2, 7, and 8 as listed in the Restriction Requirement refer to both pending and canceled claims. Groups 5-6, 13-30, 35-50 as listed in the Restriction Requirement refer only to canceled claims. Claims that are still pending have been restricted as listed below.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group 1 (Claims 1, 2, and 46) drawn to a polypeptide, SEQ ID NO:1;

Group 2 (Claims 1, 2, and 47) drawn to a polypeptide, SEQ ID NO:3;

Group 3 (Claims 3-7, 9-10, 12-13, and 48) drawn to polynucleotide, SEQ ID NO:2;

Group 4 (Claims 3-7, 9-10, 12-13, and 49) drawn to polynucleotide, SEQ ID NO:4;

Group 7 (Claim 11) drawn to an antibody that binds to SEQ ID NO:1;

Group 8 (Claim 11) drawn to an antibody that binds to SEQ ID NO:3;

Group 9 (Claims 14 and 15) drawn to a method of detecting a polynucleotide, SEQ ID NO:2;

Group 10 (Claims 14 and 15) drawn to a method of detecting a polynucleotide, SEQ ID NO:4;

Group 11 (Claim 16) drawn to a different method of detecting a polynucleotide, SEQ ID NO:2;

Group 12 (Claim 16) drawn to a different method of detecting a polynucleotide, SEQ ID NO:4;

Group 31 (Claim 28) drawn to a method of screening for a compound for effectiveness at altering expression of SEQ ID NO:2;

Group 32 (Claim 28) drawn to a method of screening for a compound for effectiveness at altering expression of SEQ ID NO:4;

Group 33 (Claim 29) drawn to a method of screening for a toxicity of a compound that hybridizes to SEQ ID NO:2; and

Group 34 (Claim 29) drawn to a method of screening for a toxicity of a compound that hybridizes to SEQ ID NO:4.

Applicants n te that the Examiner has mischaracterized Claim 29 in the description of the restriction groups. Claim 29 is directed to a method of assessing toxicity of a test compound.

Applicants hereby elect, with traverse, to prosecute Group 4, which includes and is drawn to Claims 3-7, 9-10, 12-13, and 49. Applicants also traverse the restriction requirement to elect a particular SEQ ID NO:. Applicants provisionally elect the portion of Claims 3-7, 9-10, and 12-13 directed to SEQ ID NO: 4 (encoding SEQ ID NO:3), also with traverse.

Applicants submit that the invention encompassed by the claims of Groups 3 and 4, drawn to polynucleotides, could be examined at the same time as the invention encompassed by the claims of Groups 1 and 2 without undue burden on the Examiner. For example, a search of the prior art to determine the novelty of the polynucleotides of Groups 3 and 4 would provide information regarding the novelty of the polypeptides of Groups 1and 2.

However, in addition, Applicants also traverse this restriction requirement insofar as it is, in effect, a requirement for election of species as between elements in Markush groups (those elements being, respectively, SEQ ID NO:1 and 3 with respect to the polypeptides and SEQ ID NO:2 and 4 with respect to the polynucleotides. The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (August 2001) at § 803.02 regarding restriction requirements in Markush-type claims:

> PRACTICE RE MARKUSH-TYPE CLAIMS
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> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a comm n utility, and (2) share a substantial structural feature disclosed as being essential to that utility.**

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the

> Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders bvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

It is noted that if the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to **independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement, at least as between a reasonable number of the specific sequences each in the claims is required on that basis alone.

Furthermore, **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. The polypeptides and polynucleotides of the present invention, share a common utility in, for example, toxicology studies based on expression profiling.

Moreover, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P states that "[a] Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

Finally, Examiner's attention is directed to the M.P.E.P. at § 803.04 (Restriction - Nucleotide Sequences, EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS) which states:

> Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative f rm, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restricti n requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.
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> Applicati ns claiming only a combination of nucleotide sequenc s, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

The instant application claims two polypeptide sequences (SEQ ID NO:1 and SEQ ID NO:3) and two polynucleotide sequences (SEQ ID NO:2 and SEQ ID NO:4) and the claims examined clearly should not be limited by an election of only a single sequence under the guidelines set forth in the M.P.E.P. at § 803.04.

Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:4 (encoding SEQ ID NO:3) and finding no prior art over which SEQ ID NO:4 (encoding SEQ ID NO:3) can be rejected, the Examiner must extend the search of the Markush-type claim to include the non-elected species, SEQ ID NO:2 (encoding SEQ ID NO:1).

Applicants submit that Claims 14, 15, 16, 28, and 29 (Groups 9, 10, 11, 12, 31, 32, 33, and 34) are methods of using the polynucleotides of Groups 3 and 4, which should be examined together with the polynucleotides of Groups 3 and 4, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Accordingly, because the search required to identify prior art relevant to the claims of Groups 1, 2, 3, 4, 9, 10, 11, 12, 31, 32, 33, and 34 would substantially overlap, Applicants respectfully submit that examination of Claims 1-7, 9-10, 12-16, 28-29, and 46-49, would pose

no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restricti n Requirement and xamination of Claims 1-7, 9-10, 12-16, 28-29, and 46-49. Applicants reserve the right to prosecute the subject matter of non-elected claims, or of any subject matter disclosed but not herein claimed, in a later continuation or divisional application.

It is noted that, while Applicants canceled on the Transmittal filed May 4, 2001 and not repeated new versions of the Claims 8, 17-27, and 30-45, Applicants expressly assert that these claims have been canceled for reasons relating to cost and efficiency of prosecution of the presently elected claims, and not for reasons relating to patentability. Applicants further expressly reserve the right to pursue the subject matter of those canceled claims, or any other subject matter disclosed but not herein claimed, in a later continuation or divisional application.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
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